

The drugs don't sell: DIY heart health and the over-the-counter statin experience

Article (Other)

Will, Catherine M and Weiner, Kate (2015) The drugs don't sell: DIY heart health and the over-the-counter statin experience. *Social Science and Medicine*, 131. pp. 280-288. ISSN 0037-7856

This version is available from Sussex Research Online: <http://sro.sussex.ac.uk/id/eprint/53489/>

This document is made available in accordance with publisher policies and may differ from the published version or from the version of record. If you wish to cite this item you are advised to consult the publisher's version. Please see the URL above for details on accessing the published version.

Copyright and reuse:

Sussex Research Online is a digital repository of the research output of the University.

Copyright and all moral rights to the version of the paper presented here belong to the individual author(s) and/or other copyright owners. To the extent reasonable and practicable, the material made available in SRO has been checked for eligibility before being made available.

Copies of full text items generally can be reproduced, displayed or performed and given to third parties in any format or medium for personal research or study, educational, or not-for-profit purposes without prior permission or charge, provided that the authors, title and full bibliographic details are credited, a hyperlink and/or URL is given for the original metadata page and the content is not changed in any way.

Title: The drugs don't sell: DIY heart health and the over-the-counter statin experience.

Abstract

This paper draws on a study of over-the-counter statins to provide a critical account of the figure of the 'pharmaceutical consumer' as a key actor in the pharmaceuticalisation literature. A low dose statin, promising to reduce cardiovascular risk, was reclassified to allow sale in pharmacies in the UK in 2004. We analysed professional and policy debates about the new product, promotional and sales information, and interviews with consumers and potential consumers conducted between 2008 and 2011, to consider the different consumer identities invoked by these diverse actors.

While policy makers constructed an image of 'the citizen-consumer' who would take responsibility for heart health through exercising the choice to purchase a drug that was effectively rationed on the NHS and medical professionals raised concerns about 'a flawed consumer' who was likely to misuse the product, both these groups assumed that there would be a market for the drug. By contrast, those who bought the product or potentially fell within its target market might appear as 'health consumers', seeking out and paying for different food and lifestyle products and services, including those targeting high cholesterol. However, they were reluctant 'pharmaceutical consumers' who either preferred to take medication on the advice of a doctor, or sought to minimize medicine use.

In comparison to previous studies, our analysis builds understanding of individual consumers in a market, rather than collective action for access to drugs (or, less commonly, compensation for adverse effects). Where some theories of pharmaceuticalisation have presented consumers as creating pressure for expanding markets, our data suggests that sociologists should be cautious about assuming there will be demand for new pharmaceutical products, especially those aimed at prevention or asymptomatic conditions, even in burgeoning health markets.

Keywords: UK; consumer; citizen; patient; flawed; pharmaceutical; choice; OTC

This paper draws on a study of over-the-counter statins to provide a critical account of the figure of the 'pharmaceutical consumer' in the UK. Statins, a class of drugs that reduces blood cholesterol levels, have been available on prescription since the early 1990s. In the UK, as elsewhere, they have become a major part of cardiovascular prevention, constituting an important class of prophylactic medication (Greene, 2007). Indeed, they have been cited as a textbook case of pharmaceuticalisation, representing a rapidly expanding market of drugs for people who do not see themselves as ill (Abraham 2010a). In 2004 a low dose statin (10 mg simvastatin) was licensed for sale over-the-counter (OTC), that is through pharmacies but without a prescription, in the UK. This 'reclassification' of statins appeared to open a new site for pharmaceutical consumption, allowing both direct to consumer advertising (otherwise impossible in the European market) and direct purchase of a significant drug class. Previous and subsequent attempts to get similar reclassification in the US failed (Tinetti, 2008), so the UK experience was particularly noteworthy; and indeed generated discussion in both medicine and social science.

In sociology, a debate about the drivers of the reclassification focussed on the role of state or commercial actors in bringing about such deregulation of pharmaceuticals (Abraham 2007, Edgely 2007, Moncrieff 2007). In this discussion, not unreasonably, there was little reference to consumers, but the contributors apparently assumed that there would be a market. Though **lay activism and consumerism** are described as playing a part in the expansion of pharmaceutical use (Abraham 2010b, Bell and Figert 2012, Williams, Martin and Gabe 2011), there is more to do to understand pharmaceutical consumers and consumerism.

Collective consumer action with the aim of gaining access to drugs has received attention in the pharmaceuticalisation literature and can draw on sociological studies of patient activism, which describe campaigns in relation to the regulation and reimbursement of prescription medication for conditions like AIDS or cancer (Epstein

1996, Gibbon 2007). Other studies suggest the ways in which commercial companies help create such demand through direct marketing as well as clinical research that builds awareness of their products and expands indications (e.g. Dumit 2012) and through alliances with patient groups (e.g. Moreira 2010). As Abraham (2010b) points out however there is also a tradition of activism by those claiming to have been injured by pharmaceutical products.

This paper sets out to explore the figure of the individual consumer, as figured in policy, marketing and in lay accounts.¹ To date, the pharmaceuticalisation literature has drawn on cases where drugs come to be accepted as the 'solution' to people's problems, even when these are not initially clearly accepted medical conditions. A good example is the treatment of anxiety (Williams et al 2011) as well as sexual dysfunction or weight loss (e.g. Fishman 2004; Fox, Ward and O'Rourke 2005a; Fox 2006) and products promising physical 'enhancement' (Williams et al 2011). However lay people's suspicion of both prescription and non-prescription medicines is an established theme in medical sociology.

In one review, Pound, Britten, Morgan et al (2005) suggest that while some accept pharmaceutical treatment, lay responses to medicine are best characterised by the concept of resistance. This may operate at conceptual and practical levels (Authors, in review). As Pound et al (2005) elaborate, people may be reluctant to take medicines for many reasons: concern about side-effects and dependency, the potential disruption of regimens to daily routine, a preference for more 'natural' therapies, the symbolic association of medicines with illness and thus an illness identity, as well as potential stigma associated with taking medicines (see also Hansen and Hansen 2006; Norreslet, Jemec and Traulsen 2010). At a practical level Pound et al (2005) highlight the way people reportedly modify regimens, for example lowering dose or taking 'drug holidays', as well as demurring to have prescriptions filled, not initiating or discontinuing use. While this form of individual or uncoordinated resistance to, or at least ambivalence

about medicines has been acknowledged within recent work on pharmaceuticalisation (see Williams, Gabe and Martin 2012), it casts some doubt on explanations that focus on consumer driven 'demand' across a range of drug classes.

The issues that sociologists have identified with resistance are well-known in medicine which has its own discourse of the phenomena of non-adherence. For example evidence suggests that adherence to prescription statins is low, possibly lower than fifty per cent (Benner, Glynn, Mogun et al, 2002; Mantel-Teeuwisse, 2004). The solution there is said to lie in better communication between patient and prescriber so that a drug is taken in 'concordance' with a jointly agreed regimen. Yet it has been suggested that patients may be making more independent choices, as more reflexive, active approaches to healthcare, together with the availability of drugs online, facilitate a 'consumerist' approach (Fox et al 2005a; Lupton, Donaldson and Lloyd, 1991. In the case of pharmaceuticals, such consumerism has been defined as a situation where 'healthcare consumers perceive pharmaceutical technology as an adjunct in the pursuit of a better lifestyle and experience of embodiment' (Fox et al 2005b, p1482). Here 'resisting consumers' were those who sought out drugs like Viagra or Orlistat (for weight loss) but used them in ways that countered biomedical knowledge, in contrast to 'expert patients' whose use was in line with professional understanding (Fox 2006).

Other authors have used the language of 'citizenship' to view such active approaches to healthcare through the lens of political rights and responsibilities. An emerging literature using the concept of 'biological citizenship' proposes that health and illness become central to new identities (Rose and Novas, 2005). Within this framework debates about access to drugs are part of the elaboration of the relationship between State and individual. In the case of AIDS drugs in Brazil for example, Biehl (2007) has argued that people's claims to treatment alongside marketization helped frame health policy around the provision of drugs. However, within this literature, as in pharmaceuticalisation, case studies often seem to emphasise the importance of

collective consumer action over individual meaning, and do not help explain the co-existence of both resistance and demand.

In offering our own case study here – telling the story of the OTC statins in the UK – we wish to further understanding of the individual pharmaceutical consumer. We draw attention to the expectations of consumer demand and ways of imagining the OTC statin consumer, as articulated by policy makers and professionals. However we then set these expectations against low sales and lay people's talk about drugs as a somewhat problematic product. In looking for different versions of the individual consumer in this single case we therefore present data on pharmaceutical 'consumerism' and reflect on their relevance for theories of pharmaceuticalisation more broadly.

Method

The paper draws on two parallel projects concerned with cholesterol management, designed as comparative cases and carried out consecutively between 2008 and 2011. The work was conceived as an exploration of the role of consumer health technologies for cholesterol management and their relation to health service provision. The first project focussed on functional foods such as spreads, drinks and yoghurts containing phytosterols for cholesterol reduction and the second focussed on over-the-counter and prescription statins for people at moderate risk of heart disease. We analysed professional, policy and marketing discussions around the introduction of these technologies and carried out interviews with self-identified 'users'. Data from both the projects turn out to be highly relevant to understanding the story of OTC statins in the UK.

In the first study, we interviewed 45 people recruited on the basis that they had bought or eaten functional foods containing phytosterols. In the second study we interviewed 44 people, recruited on the basis that they had bought or been prescribed a low-dose statin. Seven of these had bought the over-the-counter statin, all other respondents

from both studies might be thought of as potential OTC statin users. At the outset it was not clear whether users of foods and drugs constituted distinct groups. In fact, there was a great deal of overlap in those we recruited. Nearly half those using phytosterols said they took or had taken statins and those recruited on the basis that they had taken a low dose statin also engaged in various dietary practices to manage cholesterol. In a handful of cases this included buying foods containing phytosterols, including two in our OTC statin group. Despite this overlap, in reporting on the interviews, respondents are identified according to the project from which they originate - Phyt indicates phytosterol project; Stat indicates statin project.

Our respondents were recruited through advertisements in our own universities and the newsletters of elders forums and councils in three localities in England. After local recruitment proved difficult, users of OTC statins were recruited at a national level, using an ad appearing with a Google search for 'Heart pro' or 'Zocor'. Participants were chosen from a reasonably large pool of potential recruits to provide diversity on age, gender and occupational background. Ages ranged from 24 to 85 years, but most were over forty as might be expected (mean=64). Participants had a wide range of occupational backgrounds although there was a high proportion with professional and managerial backgrounds. Ethical review was carried out at the authors' institutions before data collection started.

Interviews in study one were conducted by author 2 and by both authors in study two. These were conducted in a variety of settings as convenient to the interviewees, including in their homes, in the authors' offices and in public spaces such as cafes. All were recorded on digital voice recorders and transcribed. These were semi-structured interviews drawing on a topic guide devised in advance. Interviews addressed how people come to have their cholesterol tested, how they come to be offered or purchase a statin or phytosterol food, how they decided whether to start and continue such use,

their interactions with health professionals and their wider household practices around cholesterol and health.

We also gathered professional, policy and marketing discussions around the introduction of the OTC statins. Material was identified through searches of the biomedical literature and more general web-based searching to identify relevant policy documents, speeches and pharmaceutical marketing from the print media. In addition we were able to draw on detailed responses to a consultation on the reclassification of statins published by the UK's Medicines and Healthcare Products Regulatory Agency (MHRA), with comment from medical doctors and pharmacists.

Taking these diverse datasets, we undertook an iterative thematic analysis in the way proposed by Hammersley and Atkinson (1995) which involved going backwards and forwards between the datasets, and specific individuals or documents within them, to identify recurrent ideas or narratives about how and why people acquire or do not acquire statins. In this paper we first report on the expectations surrounding the reclassification of statins and the introduction of the OTC product drawing on policy documents, the MHRA consultation and marketing material for the product. In analysing these we are interested in the types of responsibilities, capacities and practices ascribed to putative users in these texts and the different versions of consumer or patient invoked. We then turn to the accounts of people who are engaged in cholesterol management and focus on the way in which they position themselves as acting according to 'consumer' or 'patient' logics. Aware that health may have limited salience in everyday life (Calnan and Williams, 1991), particularly in an area as prosaic as cholesterol management, we did not expect respondents consciously to adopt strong and coherent positions or identities in relation to health consumption. Yet in carrying out our analysis we were attuned to different moments during the interviews that were suggestive of implicit identity work (McDonald, Mead, Cheraghi-Sohi et al 2007).

1. Policy narratives: giving citizen-consumers choice

In the UK, national guidelines advise that those at more than 20% risk of cardiovascular disease over ten years should be offered prescription statins within the National Health Service (NHS) (NICE 2008). This effectively continues a policy of rationing or cost-containment (Will, 2005). Initial policy statements about the possibility of reclassification emphasised that a new market would allow people 'at moderate risk' (10-15 percent over 10 years) to access the drugs. John Reid, then Secretary of State for Health was quoted in the press release announcing the change:

“We have already seen a 23% fall in premature death rates from heart disease and stroke over the past five years, on line to meet our target of a 40% reduction by 2010. This new move will allow more people to protect themselves from the risk of coronary heart disease and heart attacks. By extending access to this drug we are giving people more choice about how they protect their health. We are committed to extending choice whenever advised it is safe to do so...” (MHRA, 2004)

The extension of the statin market was thus linked in policy discourse to rationales of self-care ('allowing people to protect themselves') and 'choice'. These are the hallmarks of what has been described (Clarke, Newman, Smith et al, 2007) as the 'citizen-consumer', a key figure in the reform of public services under the New Labour government (1997-2010). Such citizen-consumers were encouraged to become 'fully engaged' in both therapeutic health care and prevention (Wanless, 2002, 2004) taking responsibility for their present and future health, and helping manage demand for funded services.

While prescribed statins were paid for in the main by the State (a relatively small prescription charge is levied with each prescription), it was expected that a new group of citizen-consumers would buy the drugs directly, picking up where publicly funded

healthcare left off. OTC purchase from pharmacists, who would carry out a minimal risk assessment (see Figure 1), was clearly linked to reducing pressure on statutory health services (Department of Health 2005) by diverting large numbers of middle aged men and women away from their doctor and a prescription. As NHS practice was expected to continue as normal, the reclassification therefore embodied a version of consumption that was compatible with communitarian logics of making only reasonable demands on statutory services (McDonald et al 2007).

FIGURE 1 HERE

The notion of 'choice' was not further elaborated in policy. The reclassification proposal gave a special role to pharmacists who would carry out the risk assessment and give lifestyle advice before selling the drug. This pharmacy-based public health was *in addition to* - not an alternative to - advice on lifestyle change at the population level. Within the range of services to be offered by pharmacies, discussions about OTC statins appeared alongside advice on smoking cessation and weight loss (Department of Health 2005). At the level of the individual however extending 'choice about how they protect their health' appeared to hold out the possibility that people might buy statins instead of making changes to lifestyle. This was of great concern to professionals commenting on the switch.

2. Professional narratives: flawed consumers in a flawed market

In examining the figure of the OTC statin consumer from the perspective of healthcare professionals we draw on responses to the consultation about the switch, organised by the UK's drug regulators (MHRA, 2003). These responses testify to a wide range of different attitudes, within which a slight majority expressed concern about the switch or recommended proceeding with caution, in part because of worries about how the product would be used.

Pharmacists and pharmacy companies were most likely to be supportive of the new product, in terms similar to policymakers:

'If this request is granted, patients will have better access to this proven medicine and a reduction in deaths from CHD could be expected to follow. The 'worried well' could be taken out of the NHS loop.' (Boots)

'[The reclassification] gives consumers access to this drug to self medicate where they may consider their risk factors are significant.' (Guild of Healthcare Pharmacists)

Though both supportive, these quotes had different implications. While Boots talked of 'patients', the Guild of Healthcare Pharmacists invoked 'consumers'. Furthermore, though Boots described a market among 'the worried well' suggesting these were people who were unnecessarily anxious about heart health, the second quote supported the idea that individuals should act on their own response to risk, a relatively abstract notion.

Questions about the cost of the drugs also divided opinion. On one hand some argued that if the drugs were beneficial then they should be provided on the NHS to avoid excluding people who could not afford the new product. Here OTC statin consumers were imagined as a distinct group who could afford the drugs and would therefore purchase them. This would have effects on health equity.

'Patients who can afford to buy the drug will do so, risking a two-tier health service in terms of access.' (Canterbury and Coastal PCT²)

On the other hand it was suggested that rational consumers would ask for prescription statins, increasing costs for the NHS:

'It is to be questioned whether the public would continue to take and purchase simvastatin over the counter for an indefinite period and whether there would be the tendency for the patient once started to request the product on a prescription.' (Exeter PCT)

Here a market was imagined, but it might be short lived if demanding consumers put pressure on general practitioners to prescribe and sought to exit the market.

Other clinical concerns also suggested a kind of distrust of users of an OTC product. For example, making a choice might mean abandoning behaviour change:

'Patients may choose to use drugs rather than addressing other important factors such as diet, or perhaps think they can eat as normal if they take medication.' (Pharmacist, New Cross Hospital)

Poor compliance, as with prescription drugs, would leave people at risk and 'lead to consumers developing a false sense of security' (Southport and Formby PCT). For others, there was a risk that enthusiastic consumption of the OTC product would lead to dangerous interactions with 'dietary and nutritional supplements' (Royal College of Physicians).

Many professionals and their organisations, then, rejected the expansion of market logics in prevention and the shift from patient to consumer relations that this entailed. They suggested that health services are better provided on the basis of rationally defined entitlements (citizenship) than (consumer) choices in a marketplace. In their discussions, both users and non-users of over the counter statins were depicted as flawed consumers (Bauman 2005): the poorest were excluded altogether, but others were expected to make bad choices, taking either too much medication or too little, or

choosing to take a pill and abandon healthy lifestyles, either due to lack of information or the moral strength to resist easy 'answers in a bottle'. The answer was to continue to require a prescription for statin use.

'We feel that the risk benefit ratio of using this drug cannot be properly assessed without specialist clinical input.' (Consultant Cardiologist, Royal Wolverhampton Hospitals)

3. Marketing narratives: empowered consumers taking control

Despite the concerns raised by professionals, the reclassification went ahead and a 10mg statin became available over-the-counter in 2005 under the brand name *Zocor Heart Pro*. Early marketing focussed on the risk of heart disease in relation to age. Print and television adverts started with either a man on his 45th or a woman on her 55th birthday, celebrating with champagne, holding a birthday cake or opening a card, who is shocked to learn that they now have a one in seven chance of a heart attack (see Figure 2). Consumers were presented as highly rational, weighing up the risks they are willing to live with and the risks on which they want to take action (1 in 7 is 'a risk too high for me' - see Figure 3).

Figures 2 and 3 here

In contrast to the flawed consumers of professional narratives, OTC statin users here were portrayed as ordinary, responsible people, doing their best to stay healthy, by exercising and trying to eat a balanced diet, but wanting additional ways to 'help protect their hearts' (see Figure 3). These look very similar to the proactive health consumers of policy who are making choices to look after themselves and exercise autonomy over prevention or 'take control of their heart health' (see Figure 4). The figure depicted is a middle-aged man or woman for whom 'heart health' is an identifiable concern, for

whom risks are a pertinent consideration, and who actively looks after their own health in recommended ways.

FIGURE 4 HERE

The story so far

Before turning to the views of lay users and non-users of over the counter statins, we wish to draw attention to the fact that the diverse narratives discussed so far largely shared a belief that there would be a market for the product.

These expectations, however, did not translate into sales. We have been unable to ascertain the overall size of the market. Telephone conversations with more than 80 pharmacists in high street pharmacies confirmed that sales of the product had been very low in 2010. We were also party to sales data from a major UK supermarket chain with more than one hundred pharmacies, in which mean sales for the year up to May 2007 were just 8 packets per store³. It is possible that online sales were higher. Yet the product was quietly discontinued in September 2010, suggesting that the supermarket data did reflect the wider picture.

So far, lay users, imagined as citizen-consumers, flawed or empowered consumers, have figured largely as implicated actors who have been discursively but not physically present (Clarke, 2005). In the final part of the analysis we turn to narratives from users or potential users of OTC statins, to explore the place of consumerism or consumer identities in their talk about cholesterol reduction.

4. Lay narratives: consumerism in health?

While statins have been widely used in the NHS for more than a decade (Department of Health, 2000), there is a longer history of commercial products and services linking to fears about cholesterol, from marketing for margarine and oat based cereals since the

1960s (Pollan, 2007) to pharmacy based cholesterol testing in the 1990s (Matthews, 1993), and more recently functional foods such as margarines and yoghurt drinks containing phytosterols. Yet we were uncertain how far respondents might position themselves as 'consumers' in this field. In the following sections we discuss this issue with reference to talk about choices for cholesterol reduction and notions of responsibility for heart health.

Pharmaceuticals as a commercial product

Though professionals had been concerned that OTC statins would be too expensive and exclude many consumers, the small numbers of users we interviewed were likely to talk about them as good value considering the health benefits they expected. One told us that he had stopped buying phytosterol drinks because they were expensive and did not last well compared with the OTC product, another emphasized that the drugs were worth the money:

'Nine quid⁴ for a month's supply so it wasn't too bad really.... I was earning quite good money then so, and when you think about it in terms of you know am I going to live for another ten years longer you know it's worth nine pounds a month isn't it?' (Stat 44, ex OTC user since withdrawn)

Purchase on the Internet was even cheaper, and allowed people to demonstrate further concern with value, presenting themselves as responsible consumers:

'I went to the local pharmacy and when I found out how much they were I thought urgh that's a bit expensive, am I even going to bother with doing this? But I had a look around on the Internet and I can actually buy, Zocor Heart Pro 10mg... I can buy those on the Internet through a pharmacy in Scotland and I can get them at less than I would have to pay prescription charge' (Stat 21, OTC statins).

A market for those resisting drugs

Looking to our wider set of interviews with users of functional foods and statins, it was clear that a broader market of cholesterol reduction technologies might also be accessed in efforts to avoid drugs. Stat 44, who had talked of the OTC drugs as good value, subsequently moved to purchasing both Benecol spread and a cheaper herbal remedy including phytosterols. Many other respondents talked about purchasing 'healthy' foods (such as oats, nuts and seeds, fish, 'light' products and those with added phytosterols), vitamins and supplements and enrolling in commercial fitness and weight management programmes after a high cholesterol reading. Within this market again people might talk about looking for a low cost option:

'My missus will probably get me what is on the best offer at that time. Them drinks tend to fluctuate in price and there's deals on one week... But I do have a drink every day, but I wouldn't say that it's Benecol all the time, like it can be anything. You know if she goes to [supermarket] and the [own brand] ones are cheaper that week she may get the [supermarket] ones' (Phyt39, not on statins).

A range of products, including phytosterols could be enrolled in efforts to avoid prescription statins offered by the doctor, narrated in terms familiar from the sociological literature on 'resistance' to medication, especially concerns about side effects or drug interactions.

'The doctor wanted to put me on statins, but I don't want to go on statins because of what I've read about the side-effects, so I said well give me 6 weeks to try and get it down and I joined slimming world and lost a stone and cut out [...]' (Phyt1, avoiding statins).

‘I suppose I would rather swallow the [yoghurt drink] bottle than a statin and a Q10 tablet you know, because I understand that pharmaceuticals that work very often do have some sort of side effects and after all you know I am taking other things.’ (Phyt30, avoiding statins).

Our data also include examples of people trying pills and then coming off them, or hoping to reduce or come off in the future. It was more common to assert that lifestyle change was used as a way to avoid pills than to admit to reducing lifestyle change because you were taking drugs – the scenario invoked in professional commentary (see Authors 2013 for fuller discussion). Our data thus show people exercising some consumer choices in a cholesterol market – looking for good value products and moving between functional and other foods, prescription and (sometimes) non-prescription pharmaceuticals. However while appearing quite active and reflexive in their approach to cholesterol reduction, most of our respondents did not describe themselves as entirely independent or self-reliant in this field. Interview talk intimated that they wished to share responsibility for cholesterol reduction with doctors or other professionals, who usually first raised the issue.

The activated patient or primed consumer?

For almost all our respondents, cholesterol emerged as a concern following some kind of clinical discussion, whether treatment for a separate medical condition or a health check. Contrary to the empowered consumers of marketing narratives, people did not describe themselves as starting with a desire to take control of their heart health, or generally seeking out risk assessments or cholesterol tests:

Interviewer: so you said that I think you were first prescribed the statins some time in 2008, as a result of having the test, how did the blood test come about? Did you get called in or did you go into the doctors to ask for it?

Phyt36: No I didn't, it was sort of coincidentally really. I went in for something

quite different and the doctor does, you know a blood pressure monitor, and he found my blood pressure was high which wasn't normal and ordered a blood test as well, a general one, not specifically for this. And that's when I first discovered that I'd got the cholesterol. (formerly on prescription statins, rejected)

Thus the identification of a problem with cholesterol for this woman in her late 70s had a feeling of 'coincidental' discovery. She was offered prescription statins but stopped taking them after a few months because she experienced side-effects. As described above, she then turned to phytosterols as an alternative.

Not only did people talk about cholesterol tests as initiated by health professionals, they also commonly suggested that professionals would lead on monitoring cholesterol. Though commercial home tests are now available, and pharmacy testing has been available for more than 20 years, respondents in both the phytosterol and prescription statin groups rarely sought to measure their cholesterol independently of their family doctor, though a few did make the appointment for follow up on their own initiative. Among our OTC users, two were self-monitoring and avoiding consultations with the doctor, but the rest were actively seeking conversations in general practice about cholesterol reduction. They tended to feel that they had been refused help for these problems, and 'denied' treatment. Thus the trajectory to using OTC statins was narrated not primarily in terms of choice or self-care, but with a sense that the doctor had not engaged with the question of what to do after a problematic cholesterol result.

In a sense then, even those of our respondents who appeared initially as consumers of cholesterol reduction products presented themselves as seeking to share responsibility for cholesterol management. Our data place doubts on the idea that people are motivated to act alone around a notion of 'heart health', and to the extent that they make choices that involve them in cholesterol reduction, including purchasing

commercial products, they are perhaps best understood as 'primed consumers' or 'activated patients'.

Claims on the state: the citizen-patient

In contrast with the narratives of professionals, OTC users invoked the notion of inequality in describing themselves as being excluded from state-funded healthcare. In the case of one man in his 60s, the respondent was alerted to his potential raised cholesterol through an eye test, with his optician suggesting he get a cholesterol test. The respondent attended his doctors and was told that his cholesterol was high and continued to have this monitored by his doctor, but with nothing prescribed. The respondent was aggrieved by this result, partly because he felt he deserved a reward for his good lifestyle and partly because of his awareness that others in a similar situation elsewhere had been prescribed statins on the NHS:

'And they put, you're scored on it, so as I said to my doctor, "So if I was fat, if I ate badly, smoked, didn't exercise, so my health was really going downhill then you'd help me.... So I don't know it just seems, I feel going back there and saying like I've started smoking, I've given up exercise can I have some statins? ... I have another friend whose cholesterol has never been as high as mine...His doctor prescribes him no problem. He's very much the same as me, you know pretty fit, same age group, it's just my particular surgery won't give, I'm going to go back and see them, now I can't [buy OTC statins]' (Stat 24, OTC statins)

Even for this OTC user, who struck quite an independent attitude, statin taking was framed as part of a conversation with a doctor. In this case, a sense of entitlement to the drugs was linked to the argument that the respondent had already made what lifestyle change he could as well as a sense that access to the treatment should be equitable across the NHS. Rather than acting in the mode of a citizen-consumer, making choices to take responsibility for their own health, some purchasers of OTC statins

appear as 'have nots', excluded from access to prescription statins (after Wyatt, 2005), and narrating this in the mode of the citizen-patient, in terms of entitlements to statutory health service on the basis of equality or merit.

This narrative of entitlement found parallels in a small set of accounts from people who had been offered prescription statins but wanted to try ostensibly better but more expensive drugs within this class. Again, respondents appeared to be acting in the mode of citizen-patients, narrating their entitlement with reference to their life-long contributions to the national purse or by making comparisons with those less deserving or less hard working.

Discussion and conclusions

In this paper we have narrated the story of OTC statins as one of high expectations from both policy and commercial sectors, and lack of enthusiasm from professionals and potential consumers. In policy, the statin reclassification appeared to fit with wider concerns to limit state support to those in greatest need, leaving 'citizen-consumers' (Clarke et al 2007) to make responsible choices in the space around these essential services. The marketing discussion also invoked the notion of choice as a rational and responsible action for those at risk. Most medical professionals and pharmacists also assumed that there would be a market for OTC statins, even as they invoked 'flawed consumers'. Though these were not imagined to be the poor (c.f. Bauman) - who were excluded entirely – it was feared that people who could afford the product would make bad choices after purchase, like relying on drugs instead of making lifestyle changes, or taking too many or too few medications to see real benefit. Interestingly these were the very arguments made in FDA hearings on a series of reclassification proposals in the USA (Tinetti, 2008).

Comparing these 'expectations' of users with our interview data, we reported first on the very limited numbers of people who ever purchased OTC statins. This was not

because people refused to see themselves as consumers. Many of our respondents in both samples were purchasing a wide variety of products for heart health, making active choices between different foods and drugs on the basis of cost and convenience. However their focus was often cholesterol rather than the more abstract 'risk' that featured in OTC statin advertising. There was a market for cholesterol reduction, but the choices made in this market speak to continued resistance to the use of medication, as predicted by the work of Pound et al (2005) and others. Our 'resisting consumers' are, therefore, of a different sort to those identified by Fox (2006) who use pharmaceuticals in the context of their own explanatory frameworks and may reject medical models. In contrast, while biomedical models were largely accepted, over the counter statins were resisted – we found 'anything-but-pharmaceuticals' consumers.

We suggest that for preventive medication at least, this resistance is still an important aspect of pharmaceutical consumerism, and goes a long way to explaining the failure of OTC statins in the UK. However we have also pointed to other reasons why the product struggled to find a market. Even when people accepted the idea of preventive medication, this acceptance almost always followed a cholesterol test. Such tests were most commonly done in the clinic and people continued to associate cholesterol management and monitoring with their general practitioner, not with pharmacists; these respondents continued to seek mediation for pharmaceutical use rather than act independently. Our data supports the argument made by many that the language of consumption obscures patients' preference for placing 'trust' in doctors (e.g. Lupton et al, 1991; MacDonald et al, 2007) and sharing responsibility for health decisions (e.g. Henwood, Wyatt, Hart and Smith 2003; Lupton 1997). Even when people started with commercial products, they might seek to get prescription statins subsequently. OTC users were not necessarily willing entrants to the pharmaceutical market, but sometimes bought statins grudgingly feeling excluded from statutory provision. The preference for prescription statins seemed to be associated both with cost and a sense

of entitlement to care within a national health service, positioning users as 'citizens'. This left little space for a 'consumer' account of their approach to pharmaceuticals.

Though the literature on pharmaceuticalisation emphasises consumer demand and action, our data therefore suggest the continued importance of health care professionals both warranting drug use and advising on health. In contrast to the notions of resisting consumers and expert or compliant patients, we have suggested the idea of the activated patient or the primed consumer, who may wish to take control of managing aspects of their health following their own rationales, but do so following professional prompting. The concept draws attention to the chronology and process of 'activeness'. People do not appear in our data as simply one or other 'type' but rather take up particular positions within a continued clinical relationship. In our case study it appears to take certain sorts of interactions for patients/consumers to gain and sustain interest in cholesterol management and thus to consider medication.

Given the failure of the OTC statin experiment, where the drugs did not sell, we suggest we should be cautious about assuming there will be a market for new drugs, especially in the area of prevention or risk reduction, when non-pharmaceutical products appear to offer solutions to the same problems, or when a social healthcare system offers cheaper prescription alternatives. As studies of 'biological citizenship' around the world suggest, a sense of entitlement to drugs can be established even in other healthcare systems around particular medical conditions such as HIV and AIDS.

We end though with questions about the reclassification debates that keep re-emerging in the US context. The repeated failure of the companies to get approval for statin reclassification there is intriguing: there is already direct-to-consumer advertising and potential consumers may be more used to paying for medicines and more interested in avoiding the cost of health care consultations. However professional concerns about 'flawed consumers' seem to have had greater weight in this context, perhaps partly

because they are not balanced by a state interested in limiting prescription costs. If statins are licensed for OTC sale in the future – and the proposals keep reappearing as prescription statins come off-patent – we will see if they sell there, or elsewhere.

References

- Abraham, J. (2007), ' From Evidence to Theory - Neo-liberal corporate bias as a framework for understanding UK pharmaceuticals regulation: response to Alison Edgley.' *Social Theory and Health.*, 5 (2): 161-175.
- Abraham, J. (2010a) The sociological concomitants of the pharmaceutical industry and medications. In: Bird, C.E., Conrad, P., Fremont A.M. & Timmermans, S. (eds) *Handbook of medical sociology* (Nashville: Vanderbilt University Press): 290-308.
- Abraham, J. (2010b) 'Pharmaceuticalization of Society in Context: Theoretical, Empirical and Health Dimensions', *Sociology*, 44 (4): 603-622.
- Bauman, Z. (2005) *Work, consumerism and the new poor*, 2nd Edition, Maidenhead: Open University Press.
- Benner, J.S., Glynn R.J., Mogun H., Neumann P.J., Weinstein M.C. and Avorn, J. (2002) Long term persistence in use of statin therapy in elderly patients. *Journal of the American Medical Association* 288: 455-461.
- Bell, S. and Figert, A (2012) "Medicalization and Pharmaceuticalization at the Intersections: Looking Backward, Sideways and Forward." *Social Science and Medicine*, 75 (5): 775-783.
- Biehl, J. (2008). Drugs for all: the future of global AIDS treatment. *Medical Anthropology* 27(2), 99-105.
- Calnan, M. and Williams, S. (1991), 'Style of life and the salience of health: an exploratory study of health related practices in households from differing socio-economic circumstances', *Sociology of Health & Illness*, Vol. 13, No. 4, pp. 506-29.
- Clarke AE. (2005). *Situational analysis: Grounded theory after the postmodern turn*. Thousand Oaks, CA: Sage.

- Clarke, J., Newman, J., Smith, N., Vidler, E. and Westmarland, L. (2007) *Creating Citizen-Consumers: Changing Publics and Changing Public Services*, London: Sage.
- Department of Health (2000), 'National Service Framework for Coronary Heart Disease: Modern Standards and Service Models', London, Department of Health.
- Department of Health (2005) *Choosing health through pharmacy. A programme for pharmaceutical public health*.
- Dumit, J. (2012) *Drugs for Life: How Pharmaceutical Companies Define Our Health* Durham: Duke University Press,
- Epstein, S. (1996) *Impure Science: AIDS, Activism, and the Politics of Knowledge*, Berkley: University of California Press
- Edgely, A., (2007). 'A spoonful of regulation helps the medicine go down': the changing face of medicine regulation *Social Theory and Health*. 5(2), 145-160
- Fishman, Jennifer R. (2004) "Manufacturing Desire: The Commodification of Female Sexual Dysfunction." *Social Studies of Science* 34(2): 187-218.
- Fox, N.J., Ward, K.J. and O'Rourke, A.J. (2005a) The 'Expert Patient': empowerment or medical dominance? The Case of Weight Loss, pharmaceutical drugs and the Internet', *Social Science and Medicine*, 60 (6): 1299-1309.
- Fox, N.J., Ward, K.J. and O'Rourke, A.J. (2005b), 'The birth of the e-clinic. Continuity or transformation in the UK governance of pharmaceutical consumption? *Social Science and Medicine* 61, 1474-1484
- Fox, NJ (2006) 'Health Identities: From Expert Patient to Resisting Consumer', *Health*, 10 (4): 461-479.
- Gibbon, S. (2007). 'Charity, breast cancer activism and the iconic figure of the BRCA carrier' in Gibbon, S. & Novas, C. (eds) *Biosocialities, Identity and the Social Sciences*, Routledge, London.
- Greene, J. (2007) *Prescribing by Numbers: Drugs and the Definition of Disease*, (Baltimore: Johns Hopkins University Press).
- Hammersley, M. and Atkinson, P. (1995), *Ethnography: Principles in Practice*, (London: Routledge).

- Hansen, D.L. and Hansen, E.H., (2006). Caught in a balancing act: parents' dilemmas regarding their ADHD child's treatment with stimulant medication. *Qualitative Health Research* 16(9): 1267-1285.
- Henwood, F., Wyatts, S., Hart, A. and Smith, J. (2003), 'Ignorance is bliss sometimes': constraints on the emergence of the 'informed patient' in the changing landscapes of health information', *Sociology of Health and Illness*, 25, 6, 589-607.
- Lupton, D., Donaldson, C. and Lloyd, P. (1991), 'Caveat emptor or blissful ignorance? Patients and the consumerist ethos', *Social Science & Medicine*, 33, 5, 559-568.
- Lupton, D. (1997), 'Consumerism, reflexivity and the medical encounter', *Social Science & Medicine*, 43, 3, 373-381.
- McDonald, R., Mead, N., Cheraghi-Sohi, S., Bower, P., Whalley, D. and Roland, M. (2007), 'Governing the ethical consumer: identity, choice and the primary care medical encounter', *Sociology of Health & Illness*, 29, 3, 430-456.
- Mantel-Teeuwisse A.K., Goettsch W.G., Klungel O.H., de Boer A. and Herings R.M. (2004) Long term persistence with statin treatment in daily medical practice. *Heart* 90:1065-6.
- Matthews, P. (1993) Is 'knowing your number worth it?' *The Independent*. London. August 22
- MHRA (2003) Consultation ARM 18, <http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/ARMs/CON007750>, accessed 27/9/13.
- MHRA (2004) Heart drug available without prescription, Press Release, <http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON002050>, accessed 27/9/13.
- Moncrieff, J. (2007). [Response to 'A Spoonful of Regulation Helps the Medicine Go Down'](#). *Social Theory and Health*, 5, 176-179.
- Moreira, T. (2010). 'When are trials not enough? Clinical versus cost-effectiveness in the controversy over access to dementia drugs in the NHS.' In Will and Moreira eds.

- Medical Proofs, Social experiments. Clinical trials in shifting contexts.* Aldershot, Ashgate. 85-102.
- NICE (2008) *Lipid modification: Cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease.* (London: National Institute for Health and Clinical Excellence).
- Noerreslet, M., Jemec, G.B.E. and Traulsen, J.M. (2009), 'Involuntary autonomy: Patients' perceptions of physicians, conventional medicines and risks in the management of atopic dermatitis', *Social Science & Medicine*, 69, 9, 1409-1415.
- Rose, N. and Novas, C. (2005). 'Biological Citizenship.' In Ong, A. and Collier, S. eds. *Global Assemblages: Technology, Politics and Ethics as Anthropological Problems.* London: Blackwell.
- Petryna, A., Lakoff, A. and Kleinman, A. (eds). (2006) *Global pharmaceuticals: ethics, markets, practices.* Durham, Duke University Press.
- Pollan, M. (2007), 'Unhappy meals', *The New York Times*, New York.
- Pound, P., Britten, N., Morgan, M., Yardley, L., Pope, C., Daker-White, G. and Campbell, R. (2005), 'Resisting medicines: a synthesis of qualitative studies of medicine taking', *Social Science & Medicine*, 61: 133-155.
- Tinetti, M. (2008) Over-the-counter sales of statins and other drugs for asymptomatic conditions, *New England Journal of Medicine*, 358, 25, 2728-2732
- Wanless, D. (2002). *Securing our Future Health: Taking a Long-Term View*, London, HM Treasury.
- Wanless, D. (2004) *Securing good health for the whole population: Final report.* London, HM Treasury.
- Will, C.M. (2005), 'Arguing about the evidence: readers, writers and inscription devices in coronary heart disease risk assessment,' *Sociology of Health & Illness* 27, 780-801.
- Williams, S.J., Martin, P. and Gabe, J. (2011) The pharmaceuticalisation of society? A framework for analysis, *Sociology of Health & Illness*, 33 (5): 710-725.

- Williams, S., Gabe, J. and Martin, P. (2012) Medicalization and pharmaceuticalization at the intersections: A commentary on Bell and Figert, *Social Science & Medicine*, 75, 12, 2129–2130
- Wyatt, S. (2005), 'Non-users also matter: the construction of users and non-users of the Internet', in Oudshoorn, N. and Pinch, T. (eds.), *How users matter: the co-construction of users and technology*, (Cambridge, Mass: MIT Press): 67-79.

¹ The individual consumer remains somewhat obscure in work on the expanding indications for drugs in Europe and the US (e.g. Greene 2007; Dumit 2012) though studies of global pharmaceuticals from anthropological perspective have lots to say about individuals in Brazil, Argentina, India and elsewhere (e.g. contributions to Petryna, Lakoff and Kleinman, 2006).

² PCT: Primary Care Trust

³ One packet provides one month's supply. Average sales per store therefore equates to less than one person per store.

⁴ 'Quid' is a colloquial term for UK pounds sterling.